

105 CMR 800.000: REQUIRED REQUESTS FOR ANATOMICAL DONATIONS

Section

Substantive

- 800.001: Purpose
- 800.002: Citation
- 800.003: Scope
- 800.004: Definitions
- 800.030: Consent Procedures
- 800.035: Amendment or Revocation of Gift
- 800.036: Conditions Under Which Requests for a Donation are not Required
- 800.037: Preservation of the Potential Donor

Administration

- 800.040: Responsibilities of Hospital Administrator/Director
- 800.099: Appendices

800.001: Purpose

- (A) 105 CMR 800.000 sets forth for the purpose of interpreting and implementing M.G.L. c. 113, §§ 8 through 14.
- (B) It is the intent of the law and the regulations to establish a uniform system of requesting consent to anatomical gifts in order to increase the supply of organs and tissues for the purposes of transplantation, therapy, research and education.

800.002: Citation

105 CMR 800.000 shall be cited as 105 CMR 800.000: *Required Requests for Anatomical Donations*.

800.003: Scope

105 CMR 800.000 shall govern Requests for Consent to Anatomical Donations pursuant to M.G.L. c. 113. Any section of 105 CMR 800.000 may be severed or altered without affecting the enforceability of the remaining sections.

800.004: Definitions

As used in 105 CMR 800.004 the following terms shall have the following meanings unless the context or subject matter clearly requires a different interpretation.

Acute Hospital means any hospital licensed under M.G.L. c. 111, § 51, and the teaching hospital of the University of Massachusetts medical school, (which contain a majority of medical-surgical, pediatric, obstetric, and maternity beds), as defined by the Department of Public Health.

Brain Death means total and irreversible cessation of spontaneous brain functions and further attempts are resuscitation or continued supportive maintenance would not be successful in restoring such functions. *Commonwealth v. Golston, 373 Mass 249, 366 N.E. 2d 744, (1977)*.

Commissioner means the Commissioner of the Department of Public Health.

Consent means informed decision to grant permission for organ donation, living or post humous. Evidence of donative intent must be placed in and made part of the donor's medical record by either of the following forms of documentation:

- (1) Donor card signed by or for donor in the presence of two competent witnesses;

800.004: continued

- (2) Hospital consent form signed by person(s) of highest priority class available who is qualified to give consent and the designated representative. *See* 105 CMR 800.030(B).
- (3) (a) Recorded telephone conversation or other form of recorded telecommunication of person of highest priority qualified to give consent, reduced to writing and attested to by one witness, and the designated representative; or
(b) Telegraphic message of such person identifying the sender and relationship to potential donor.
- (4) Will - document bearing signature of decedent, completed in the presence of two competent witnesses, setting forth disposition of body or part thereof upon death.
- (5) Document other than a will such as, but not limited to, donor card signed by donor setting out specific donation.

Death or Time of Death means determination of point in time at which death occurred as certified by a physician who attends the donor, or if none; legal certification of death by a physician in keeping with currently acceptable medical criteria.

Decedent means a deceased individual and includes a stillborn infant or fetus.

Department means the Department of Public Health.

Designated Representative means a person(s) appointed by the hospital administrator/director to inform any person qualified to give consent of the opportunity to make an anatomical gift.

Donee means any person or legal entity qualified under state laws to become recipients of bodies or part thereof as listed in M.G.L. c. 113, § 9 (hospitals, physicians/surgeons, accredited medical and dental schools, colleges or universities for education and research, bank or storage facilities).

Donor means a person who has authorized or a decedent whose organ(s) or tissue(s) has been authorized for removal pursuant to the formalities of consent as stated in 105 CMR 800.030.

Hospital means a hospital licensed, accredited or approved under the laws of any state and includes a hospital operated by the United States government, a state or a subdivision thereof, although not required to be licensed under state laws.

Initial Medical Criteria means the standards for screening potential donors established by the New England Organ Bank. A copy of these criteria shall be available from the Department.

Living Donor means a person who by a document other than a will makes a gift of his/her body part for the purpose of transplantation at such time prior to death as specified in said document.

Minimal Preservation Procedure means technique, including administration of preservation fluid, by which the organ(s) and/or tissue(s) of a potential donor is preserved for future transplantation. *See* 105 CMR 800.037.

Order of Priority means ranking of person(s) qualified for the purpose of consent who is authorized or under obligation to dispose of the body of the decedent.

Organ or Tissue Bank or Storage Facility means a hospital, laboratory or other facility licensed or approved by the Department for storage of human bodies or parts thereof, for use in medical education, research, therapy or transplantation to individuals.

Part means organs, tissues, (skin, eyes, bones, arteries, blood or other body fluids) and other portions of a human body; and "part" includes "parts".

Person means an individual, corporation, government or governmental subdivision or agency, business trust, estate trust, partnership, association, or any other legal entity.

800.001: continued

Physician or Surgeon mean a physician or surgeon licensed or authorized to practice under the laws of any state.

Pre-mortem Tests means any examinations, tests, or procedures performed after consent is given prior to death that are determined necessary to assure medical acceptability of the gift for purpose(s) intended by the donor.

Potential Donor means a person who meets the initial medical criteria for screening.

Record of Donations means book kept by hospital for the purpose of recording anatomical gifts as required by M.G.L. c. 113, § 8(c).

State means any state, commonwealth, district, territory, insular possession, and any other area subject to the legislative authority of the United States of America.

Undue Emotional Stress means a state of excitation or extreme sensitivity observed in the next of kin when information about a donation is sought even under circumstances where precautions have been exercised as indicated in Conditions Under Which Requests For Donations are not Required. *See* 105 CMR 800.036.

800.030: Consent Procedures

(A) Consent Requirements for Qualified Persons. Any consent to an anatomical gift by a person as authorized in this section shall be given by a document bearing the signature of said person. Recorded telephonic or other recorded telecommunication message shall be reduced to writing and entered into the decedent's medical record. One person in addition to the designated representative shall witness and sign. Telegraphic communication shall be made a part of the donor's medical record.

Consent or refusal need only be obtained from any person in the highest priority class available, in person or by telephone, when persons in prior classes have been sought and are not available at the time of death.

(1) Documentation of a Telephone Consent Shall Include:

- (a) Date, time and telephone number called.
- (b) Name and position of the person who spoke to the decedent's relatives or legal guardian.
- (c) Name and relationship of the person called to the decedent.
- (d) A summary of the information conveyed to the person called consistent with hospital policies.
- (e) Date and time of entry in decedent record as well as the writer's signature.

(2) Classes Of Persons Qualified To Give Consent. The following order of priority is set forth for persons authorized to give consent for donation of an anatomical gift:

- (a) the spouse;
- (b) an adult son or daughter;
- (c) either parent;
- (d) an adult brother or sister;
- (e) a guardian of the decedent at the time of death;
- (f) any person authorized or under obligations to dispose of the body.

If a gift authorized by a member of a class is opposed by a member of the same or a prior class, there shall be no removal of the organ or tissue.

(3) Divorced or Separated Spouse. When the person(s) of the highest priority class available is a divorced spouse, the person qualified to give consent will be a member of the next priority class. A separated spouse if available after diligent search must explicitly waive authorization in writing or by witnessed telephonic communication before a member of a lower priority class is authorized to give consent.

(4) Unemancipated Persons and Mentally Incompetents. When a person(s) of the highest priority class available to give consent has not yet attained the age of 18, is not emancipated or is mentally incompetent, that person may not be the consenting party of record. In such case a guardian duly appointed by the court or person legally responsible (105 CMR 800.030(A)(2)) shall be the party of record. (Exception: The consent of an unmarried mother is sufficient.)

800.030: continued

(B) Consent by Donor.

(1) Gift By Will Or Other Document. Any person of sound mind who has attained the age eighteen years or older may make a gift of all of his body or part(s) thereof for either of the following purposes:

- (a) transplantation,
- (b) therapy,
- (c) medical or dental education,
- (d) advancement of medical or dental science and
- (e) research. (M.G.L. c. 113, § 9(1). Such gift(s) will take effect upon death of the donor, or at such time as specified in the document. The gift(s) may be made by a will or a document other than a will; signed by or for the donor in his presence. The signatures of two competent witnesses who have signed in the donor's presence must also appear on the document.

(2) Gift By a Living Donor. When a person of sound mind who has attained eighteen years or older makes a gift of any part of his/her body intended for transplantation, the gift shall be set out in writing signed by or for the donor in his/her presence. Such gift may take effect prior to death or at a time specified in the document.

The signatures of at least two physicians who are to participate in the transplantation operation shall appear on the document(s).

(3) Rights of Donee. The rights of the donee created by the gift are paramount to the rights of others except as provided by M.G.L. c. 113, § 13(d), subject to the laws of the Commonwealth relative to autopsies.

(C) Evidence of Donative Intent. When the potential donor has on her/his person or present among his/her immediate possession evidence of donative intent, as listed below; no additional consent is required from a person qualified to give consent before removal of an organ or tissue:

- (1) Universal donor card; or
- (2) Will-document by decedent setting out disposition of body or part thereof. The will need not be delivered to donee at the time of death for the gift to take effect; or
- (3) Entry into medical record by primary or attending physician signed by donor, and witnessed by two competent persons in the donor's presence; or
- (4) Other - legal notification of intent-any legally executed document setting forth the wishes of the donor regarding the disposition of his body upon death. Person in highest priority class available may be notified of procedure, not for the purpose of obtaining consent; rather for notice of donor's intent.

800.035: Amendment or Revocation of a Gift

Amendment or revocation of an anatomical gift may be done in any of the following ways: (M.G.L. c. 113, § 12)

- (A) If created by a will must be revoked by the formalities required by will;
- (B) An oral statement made in presence of two persons and communicated to donee;
- (C) Statement during a terminal illness or injury addressed to any physician and communicated to the donee by attending physician;
- (D) Destruction, cancellation, or mutilation of the document and all executed copies thereof;
- (E) A signed statement or document delivered to donee or found on decedent's person or among his effects expressly revoking the gift.

800.036: Conditions Under Which Requests for Donation are not Required

Pursuant to M.G.L. c. 113, § 8(d) anatomical donations shall not be requested when any of the following conditions are present:

800.036: continued

- (A) Designated representative or donee has knowledge or actual notice of contrary intentions by the decedent; or
- (B) Designated representative or donee has knowledge of or actual notice of opposition by a member of any of the classes specified in 105 CMR 800.030(A)(2); or
- (C) There is evidence or indications that such request will cause undue emotional stress to next of kin; or
- (D) There are other reasons to believe that an anatomical gift is contrary to the decedent's religious or moral beliefs.

800.037: Preservation of the Potential Donor

The purpose of 105 CMR 800.000 is to allow for a minimal preservation procedure which would maintain and make available to the family a meaningful option in an opportunity to consider a donation. (*See* 105 CMR 800.004: *Definitions*). In no case shall this procedure be construed to mean that removal of an organ or tissue may be carried out without statutory consent.

(A) When the potential donor is a Dead-on-Arrival (DOA) or a person who expires within six hours after arrival at a hospital and there is no evidence of intent to donate - donor card or other document - all means necessary shall be used to obtain consent from a person qualified to give such. No procedures to remove an organ or tissue shall be initiated without expressed consent as indicated in 105 CMR 800.030(A).

If, however, a donor card is present or found among potential donor's possessions, minimal preservation procedures may be initiated.

(B) In the case where the potential donor is under the jurisdiction of the medical examiner, removal of an organ or tissue shall be performed only after the medical examiner certifies that such removal does not in any way interfere with required medicolegal investigations and all other relevant provisions of these regulations have been satisfied.

Minimal preservation procedure shall not in any case be maintained for more than 24 hours.

800.040: Responsibilities of Hospital Administrator/Director

(A) Maintenance of Record of Request. Pursuant to M.G.L. c. 113, § 8(c) the director or person in charge of an acute hospital is responsible for maintaining documentation of all donors for whom consent to an anatomical gift was granted. The director shall keep or cause to be kept a record containing the following:

- (1) account of number of potential donors identified;
- (2) account of number of consents granted;
- (3) patients for whom consent to an anatomical gift had been granted;
- (4) the organ or tissue donated;
- (5) person(s) granting the consent;
- (6) the relationship of such person(s) to the decedent; and

(B) Establishment of Policies and Procedures. The hospital administrator/director shall assure that written policies and procedures consistent with those of organ and tissue procurement programs are established, implemented and maintained for:

- (1) identifying potential donors;
- (2) requesting consent as required in these regulations;
- (3) documentation as required herein.

800.040: continued

(C) Data Collection and Reporting. The director or person in charge of such hospital shall forward the data collected to the Department of Public Health; excluding 105 CMR 800.040(A)(3), (5) and (6), which shall be maintained by the hospital and be available upon inspection. Such data shall be forwarded on June 1 of each year to the Division of Health Statistics.

REGULATORY AUTHORITY

105 CMR 800.000: M.G.L. c. 113, §§ 8 through 14.